AD_____

Award Number: W81XWH-06-1-0254

TITLE: Inclusion of Minority Patients in Breast Cancer Clinical Trials: The Role of the Clinical Trial Environment

PRINCIPAL INVESTIGATOR: Celia P. Kaplan

CONTRACTING ORGANIZATION: University of California, San Francisco
San Francisco, CA 94118

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Fort Detrick, Maryland 21702-5012

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14. ABSTRACT
Clinical trials are the primary vehicle for transforming laboratory discoveries in breast cancer care into clinical practice. Enhanced participation by minorities in these trials is necessary to assess the effectiveness of advances in breast cancer care among major subpopulations and to ensure equity in the distribution of research benefits. However, minority participation in clinical trials will likely remain low without research designed to understand the reasons for limited participation. To address persistent ethnic and socioeconomic disparities in cancer care, including participation in research, interventions need to assess the broader context of clinical trials and include the larger community where these trials take place. Our study examines the combined effect of these factors on minority referral. Due to challenges in contacting research team members (RTMs), we have developed a protocol to randomly sample clinical trial site locations to identify 100 RTMS to survey. Final versions of the survey instruments have been developed. Lastly, a no cost extension has been obtained to complete the project due to changes in staffing and the principal investigator's leave of absence for health reasons. We have also added a new research team member to assist with the study.

15. SUBJECT TERMS
Clinical trials, minorities, health care settings, communities

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Inclusion of Minority Patients in Breast Cancer Clinical Trials:

The Role of the Clinical Trial Environment

Celia P. Kaplan, DrPH, MA, Principal Investigator

Annual Report 2008

Introduction

Clinical trials are the primary vehicle for transforming laboratory discoveries in breast cancer care into clinical practice. Enhanced participation by minorities in these trials is necessary to assess the effectiveness of advances in breast cancer care among major subpopulations and to ensure equity in the distribution of new treatment benefits. While inroads to increasing minority inclusion in breast cancer clinical trials have been made,[1-4] recent reports continue to demonstrate lower enrollment among African Americans, Asian Americans, and Latinos when compared to Whites.[5] Within the last decade, the average rate of increase in breast cancer incidence among Latinos and Asian Americans has risen,[6] underscoring the need for minority inclusion in cancer clinical trials. Minority participation will likely remain low without research designed to understand the reasons for limited participation and subsequent policy changes based on those findings. Therefore, to address persistent ethnic and socioeconomic disparities in cancer care, including participation in research, interventions need to assess the broader context or culture of clinical trials and include the larger community where these trials take place. Our study aims to examine the combined effect of these factors on minority referral. To achieve this, we will measure clinical trial characteristics that may impact minority recruitment, such as accessibility and availability of trials, site cultural competence, and outreach efforts. We will also examine the social and physical characteristics of the community surrounding the trials. Key indicators associated with clinical trial referral will be identified in order to establish the basis for a standardized methodology to assess the overall capability of clinical trial sites to include minorities. The proposed study will extend our current state of knowledge about factors affecting referral and participation of minorities in clinical trials. Results will contribute to the development of interventions aimed at clinical trial sites and those that address specific barriers associated with the social or physical environment.

Body

This annual report highlights two changes in the grant. First, Dr. Michelle Melisko has joined the research team to assist with the characterization of clinical trials eligibility and assist with the collection of study protocols and consent forms. Dr. Melisko is a medical oncologist specializing in breast cancer quality of life and clinical trial participation. Second, we have obtained a no-cost extension to complete the project. Due to changes in staffing and the principal investigator's (PI) leave of absence for health reasons, we were unable to complete all tasks within the original proposed timeline. The tasks described below represent the modified timeline.

Task 1: Identify Breast Cancer Clinical Trials (Months 1-24). To date, we have identified active breast cancer trials that are being conducted in California, Florida, Illinois, and New York listed on the Physicians Data Query (PDQ®), the National Cancer Institute's comprehensive clinical trial cancer database. As stated in the year 01 report, in order to be included in the study, clinical trials were required to be a) a breast cancer treatment trial and b) open to participation between 1 July 2006 and 30 June 2007. All identified breast cancer clinical trials were entered into an ACCESS database for a total of 225 clinical trials and 411 clinical trial sites.

Based on preliminary data analysis, we identified several key variables with missing information such as the phase of the study, eligibility criteria into the study, and co-morbidities. To ensure data integrity, we contacted the research coordinators and research team members of each clinical trial to identify the phase of the clinical trial. As to information on eligibility criteria and co-morbidities, we will be requesting consent forms and protocols from clinical trial sites. Initially, we will collect information from the USC/Norris Comprehensive Cancer Center and the UCLA Jonsson Comprehensive Cancer Center where our research team has collaborative relationships with key individuals. From there, we will develop a short protocol to collect consent forms and protocols for each remaining clinical trial and their respective trial sites.

We also noted that a select group of clinical trials administered by Community Clinical Oncology Programs (CCOP) in all four states were classified according to their administrative site instead of their actual clinical trial sites. To account for this, we contacted all eight CCOPs listed in our database to identify all breast cancer clinical trials that they administered between 1 July 2006 and 30 June 2007. We verified the respective clinical trial site locations to ensure that these sites were included in our data.

Task 2: Identify Clinical Trial Research Team Members (RTMs) (Months 1-8). We gained approval from the UCSF Committee for Human Research to conduct interviews with key informants (effective 21 December 2006; see Appendix 1). Using information gleaned from our online research, we identified key personnel in several Northern California cancer centers, including the Stanford Comprehensive Cancer Center, the Alta Bates Comprehensive Cancer Center, and the UC Davis Medical Center. We plan to conduct these RTM interviews within the first six months of the no-cost extension time period.

Task 3: Develop RTM Survey Instruments (Months 5-9). After consideration of personnel hours, staff capacity, and other factors, the research team decided to use multiple modes of survey data collection: a telephone survey, a self-administered paper survey, and an online survey. The existing RTM survey instrument was reviewed and refined to meet the current study goals. Language and presentation of the instrument were amended to reflect the multimodal approach to data collection. Key informants have pretested the survey and provided feedback.

Task 4: Conduct RTM Surveys (Months 24-30). An Access database has been created to store RTM contact information and to track progress of the data collection.

In our initial attempts, we met tremendous challenges in contacting and recruiting RTMs for participation in the study. As a result, the research team has decided to focus intensively on 100 RTMs. RTMs will be randomly selected from four sampling categories of clinical trial sites. We will randomly select 25 clinical trial sites from four clinical trial categories and attempt to contact at least one RTM from each site.. These four clinical trial sampling categories include: cancer centers (NCI-designated comprehensive cancer centers, NCI-designated cancer centers, self-designated comprehensive cancer centers, self-designated cancer centers, and American

College of Surgeons designation), hematology/oncology medical groups, teaching/university hospitals (university medical centers, university affiliated medical centers, teaching medical centers, Kaiser Permanente, university hospitals, university affiliated hospitals, and teaching hospitals), and others (medical centers, hospitals, nonprofit/research centers, pharmaceutical/CRO and other medical groups). Five sites will be selected from each of the sampling categories with the exception of ten sites from the "other category."

In addition, we will conduct a special mailing to principal investigators (PIs). PIs will have two options for taking the survey: a self-administered survey or an online survey. Regardless of how the responses are collected, they will be entered using the web-based survey data collection software. This will establish a single dataset for all RTMs, ensuring greater data integrity.

Task 5: Identify Community Indicators (Months 21-23). We have completed a review of the literature to identify appropriate geographic measurement units and relevant community indicators. Data will be collected to characterize both the physical environment and the social environment surrounding clinical trials.

The physical environment will be characterized by traffic congestion and distance from public transportation. We have already begun to identify publicly available geographic and demographic data, which includes different sources of traffic data from the State Departments of Transportation and the Texas Transportation Institute. Thus far, we have uniform indicators through data provided by the Texas Transportation Institute. We are still investigating the data provided by the State Departments of Transportation and have identified key congestion measures to characterize the physical environment. Together, these indicators will help evaluate the time burden experienced by patients accessing clinical trials.

The social environment will be characterized by the following indicators: race/ethnicity of the area, proportions of persons over 18 years who are unemployed, population density, percent of persons with annual income below the poverty line, proportion of persons over 25 years with less than a high school education, proportion of households headed by women, proportion of persons over 18 years who are divorced/separated, and percent of persons over 18 years with Medicaid or who are uninsured. Data for indicators listed in the social environment will be collected through the census.

Task 6: Identify Breast Cancer Physicians in California, Florida, Illinois, and New York (Months 22-24). We received the AMA Physicians MasterFile and identified all physicians practicing surgery, oncology, or radiation oncology in the four states. Based on the data, we have selected a random sample of 200 physicians of each specialty and each state. We set an internal physician database for tracking and following up of physician contact information using MS Access. We expect to begin the mailing process in the first week of May 2008.

Task 7: Develop and Refine Instrument for Physician Survey (Months 19-24). The physician survey has been developed and pretested. Concurrent with this, we have developed an online version using DatStat Illume, a data collection software program. Both versions have already undergone a final pre-test among five physicians before full implementation. The paper version of the survey has been professionally printed and the online version has been uploaded to the server.

Task 8: Recruit Physicians and Collect Data (Months 25-28). Paper versions of the physician surveys will be mailed to 2400 physicians (approximately 200 from each specialty, in each state) to obtain our recruitment goal of 1560 completed surveys, or a 65% response rate (Months 25-28). Physicians will receive an introductory letter with the survey. The letter will include links to the online version of the survey and a survey username and password. Regardless of data collection mode, responses will be entered using the on-line survey application. This will better ensure data integrity by establishing a single dataset for all physician responses. To follow-up with physicians who did not answer the survey, we have designed a targeted follow-up protocol that includes phone calls to doctors' offices and intensive internet searches.

Finally, to supplement the introductory letter and provide a link to the online survey instruments, the research team created a study website. This website provides physicians and RTMs with more information regarding the study design and rationale and a brief description of each of the research team members. In addition, we

updated the principal investigator's web pages at the Medical Effectiveness Research Center and the Division of General Internal Medicine to include links to the study webpage and the physician survey.

Task 9: Data analysis (Months 21-25). With regards to our mapping analysis, our effort has focused on collecting accurate address information, which is essential to accurate geocoding. We have searched for clinical trial site addresses on the internet when information was unavailable or incomplete and phoned sites to confirm their addresses. For clinical trial sites that had multiple addresses, we captured all the addresses and confirmed by phone or internet search the specific addresses where trials were taking place. To export this data from our database, we used queries for running frequencies and merging data in other applications (such as MS Word) and forms for data entry and record retrieval. Site address data were subsequently exported to ArcView 9.2, a map-making application for geocoding. With geocoding complete, we generated preliminary maps of clinical trial sites in the four states. To refine these maps further, we used standard population ranges across all four states in hopes of drawing concrete comparisons between the states with regard to clinical trial availability to minority populations. Large metropolitan areas were also mapped to help us better understand the environment of the clinical trials. Preliminary results indicate that areas with large numbers of minority populations have a low number of clinical trials.

Key Research Accomplishments

Improved the integrity of our database of active breast cancer clinical trials taking place in California, Florida, Illinois, and New York by further researching missing information, including investigating CCOP clinical trial site locations and eligibility criteria

- Refined preliminary maps of clinical trial sites in the four states
- Due to challenges with contacting RTMs, developed a protocol to randomly sample clinical trial sites in each state to identify 100 RTMs to survey
- Identified community indicators and their data sources
- Developed a paper version of the physician survey
- Developed an online version of the physician survey, including backend infrastructure.
- Selected the physician sample
- Created a website to provide physicians with more information regarding the study and the research team members

Reportable Outcomes

Not applicable

Conclusion

In Years 01 and 02, we focused on laying the foundation and building the infrastructure for this study. Through the process of our formative work, we have gathered valuable insights to inform and guide our activities for the following phase of the project.

Final revisions are being made to the surveys that will be used for data collection. The process of identifying active breast cancer clinical trials in California, Florida, Illinois, and New York is complete, and we have strengthened our data with further research to fill in missing information. Databases have been created to store the information we have gathered thus far. To characterize the physical and social environments surrounding clinical trials, we have identified relevant community indicators and their data sources. We have developed final versions of all survey instruments.

Looking back at our formative work, many of the challenges we encountered in obtaining information about clinical trials reaffirmed for us the need for research aimed at understanding the factors that influence low rates of minority participation in clinical trials. Much of the information regarding clinical trials that is widely available to the public on the internet is fragmented and not standardized, both in the ways the information is presented and what type of information is available. The task of compiling such information can be daunting, for both breast cancer patients and primary care providers. We hope this study will provide some insight into how clinical trial information and enrollment can be made more accessible, particularly to minority populations.

Though we faced some delays in the project this past year, we have adapted our protocols to continue our activities, and we look forward to beginning the data collection process.

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Appendices

Appendix 1: No Cost Extension Approval Letter

Appendix 2: UCSF Committee for Human Research Approval Letter

Appendix 3: Maps of clinical trial sites in California and New York

Appendix 4: Print version of the Physician Survey

Appendix 5: Web version of the Physician Survey

Appendix 1:
No Cost Extension Approval Letter

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

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SAN FRANCISCO, CALIFORNIA 94118
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FAX: (415) 476-8158 http://www.ucsf.edu/ora/

April 16, 2008

Cheryl A. Lowery
U.S. Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, MD 21702
Tel: (301) 619-7150
Fax: (301) 619-4084
cheryllowery@amedd.army.mil

RE: Request of a No-Cost Extension of Award W81XWH-06-1-0254

Dear Ms. Lowery:

Please be advised that the current award, which is funded under the Terms and Conditions of the Federal Demonstration Partnership, Phase IV, expires on **05/31/2008**. Dr. Kaplan is requesting a one-year no-cost extension of this project. Attached please find a copy of the request.

This will serve as the official notification to you that I have approved this request for a no-cost extension through **05/31/2009**.

Please issue a revised award or mark your acknowledgement on the bottom of this letter and return an original copy to me. If you have any questions or concerns, please contact Sean Sotelo at (415) 502-3273, by fax at (415) 476-8158 or by e-mail at sean.sotelo@ucsf.edu.

Sincerely,

D. Caulfield
actg for

Joan Kaiser
Contracts and Grants Officer

JEK/srs
Enclosures

University of California
San Francisco

UCSF

Department of Medicine
Division of General Internal Medicine

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3333 California Street, Suite 335
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tel: 415/476-6894
toll free: 888/663-6661

4/1/2008

Joan Kaiser
Director, Contracts & Grants
Office of Sponsored Research
Phone: (415) 476-8156
Fax: (415) 476-8158
Email: joan.kaiser@ucsf.edu

Re: Grant Number; W81XWH-06-1-0254 FDP (NCTE)
PI: Celia P. Kaplan, Dr. P.H.

Dear Ms. Kaiser:

I am writing this letter to request a no-cost extension for the grant titled, "Inclusion of Minority Patients in Breast Cancer Clinical Trials: The Role of the Clinical Trial Environment". We are requesting a change in the project end date from 05/31/08 to 05/31/09 to allow time for the final activities of the project to be completed. The no-cost extension is due to turnover in staffing and the PI's health-related leave of absence during year 02 that delayed some aspects of data collection.

During the no-cost time extension, we will use the estimated carry forward of $282,397.00 (direct costs) to support the PI and staff to complete the data collection, analysis, manuscript preparations, and the dissemination of research findings.

Thank you for your attention to this matter and for your approval.

Sincerely yours,

Celia P. Kaplan, Dr. P.H.
Associate Adjunct Professor/Principal Investigator

I concur,

Talmadge E. King, Jr., MD
Professor
Chair-Department of Medicine

D. Caulfield
acting for -
JOAN KAISER
CONTRACTS & GRANTS OFFICER

Cc: Solat Navab/UCSF fund#23113-DOD

Appendix 2:
UCSF Committee on Human Research
Approval Letter

COMMITTEE ON HUMAN RESEARCH
OFFICE OF RESEARCH, Box 0962
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
www.research.ucsf.edu/chr/Apply/chrApprovalCond.asp
chr@ucsf.edu
(415) 476-1814

CHR APPROVAL LETTER

TO: Celia Patricia Kaplan, Dr.P.H., M.A.
Box 0856

RE: Inclusion of Minority Patients in Breast Cancer Clinical Trials: The Role of the Clinical Trial Enviornment

The Committee on Human Research (CHR) has reviewed and approved this application to involve humans as research subjects. This included a review of all documents attached to the original copy of this letter.

Specifically, the review included but was not limited to the following documents:
Physician Consent Form, Dated 11/30/06
Key Informant Consent Form, Dated 11/30/06

The CHR is the Institutional Review Board (IRB) for UCSF and its affiliates. UCSF holds Office of Human Research Protections Federalwide Assurance number FWA00000068. See the CHR website for a list of other applicable FWA's.

APPROVAL NUMBER: H9066-27862-03. This number is a UCSF CHR number and should be used on all correspondence, consent forms and patient charts as appropriate.

APPROVAL DATE: December 4, 2007 **EXPIRATION DATE:** December 21, 2008 **Expedited Review**

GENERAL CONDITIONS OF APPROVAL: Please refer to www.research.ucsf.edu/chr/Apply/chrApprovalCond.asp for a description of the general conditions of CHR approval. In particular, the study must be renewed by the expiration date if work is to continue. Also, prior CHR approval is required before implementing any changes in the consent documents or any changes in the protocol unless those changes are required urgently for the safety of the subjects.

HIPAA "Privacy Rule" (45CFR164): This study does not involve access to, or creation or disclosure of Protected Health Information (PHI).

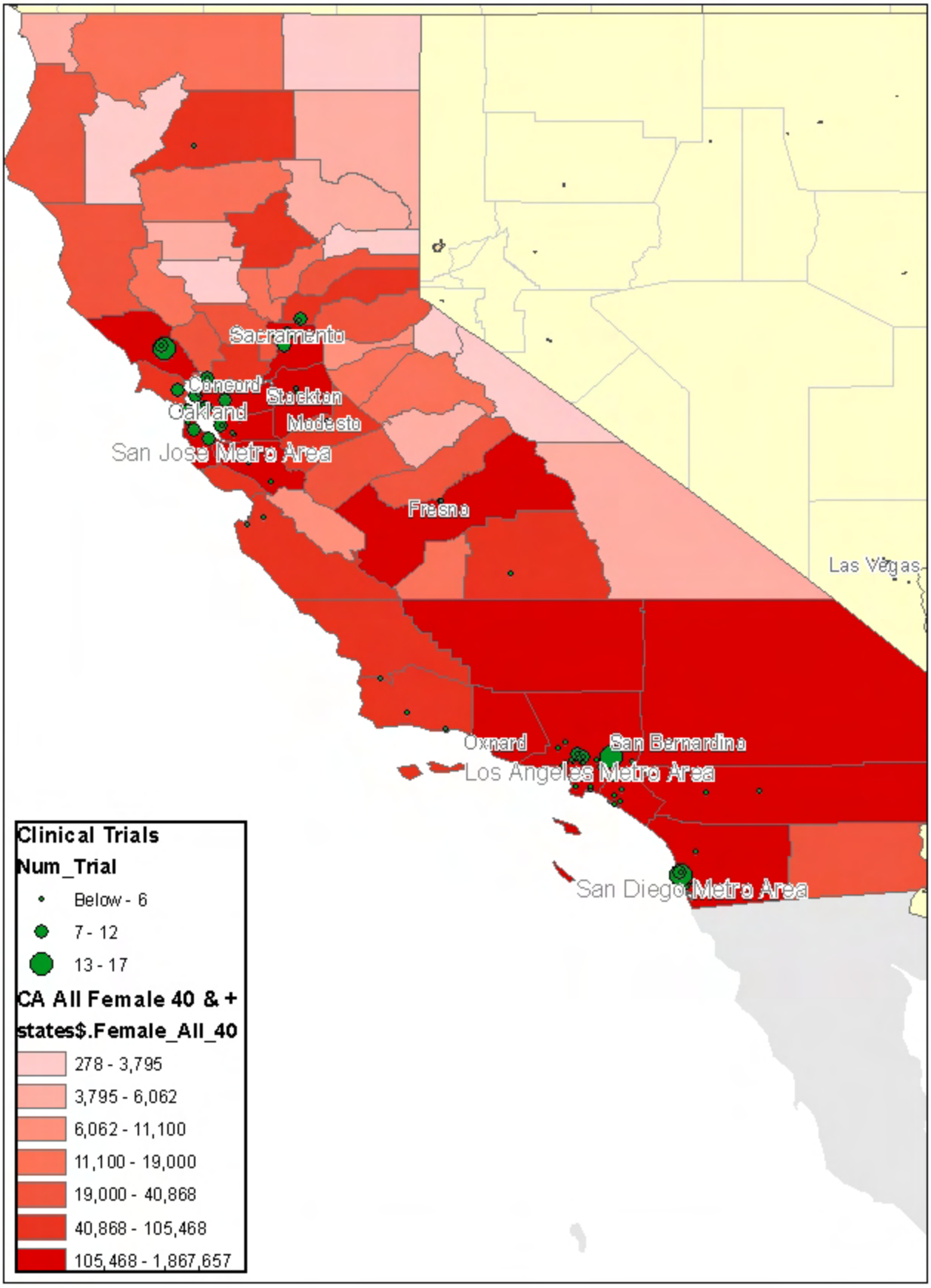
Sincerely,

Alan P Venook MD

Alan P. Venook, MD
Chair, Committee on Human Research

cc: Patrice Esser, Box 0856

Appendix 3:
Maps of clinical trial sites in California and New York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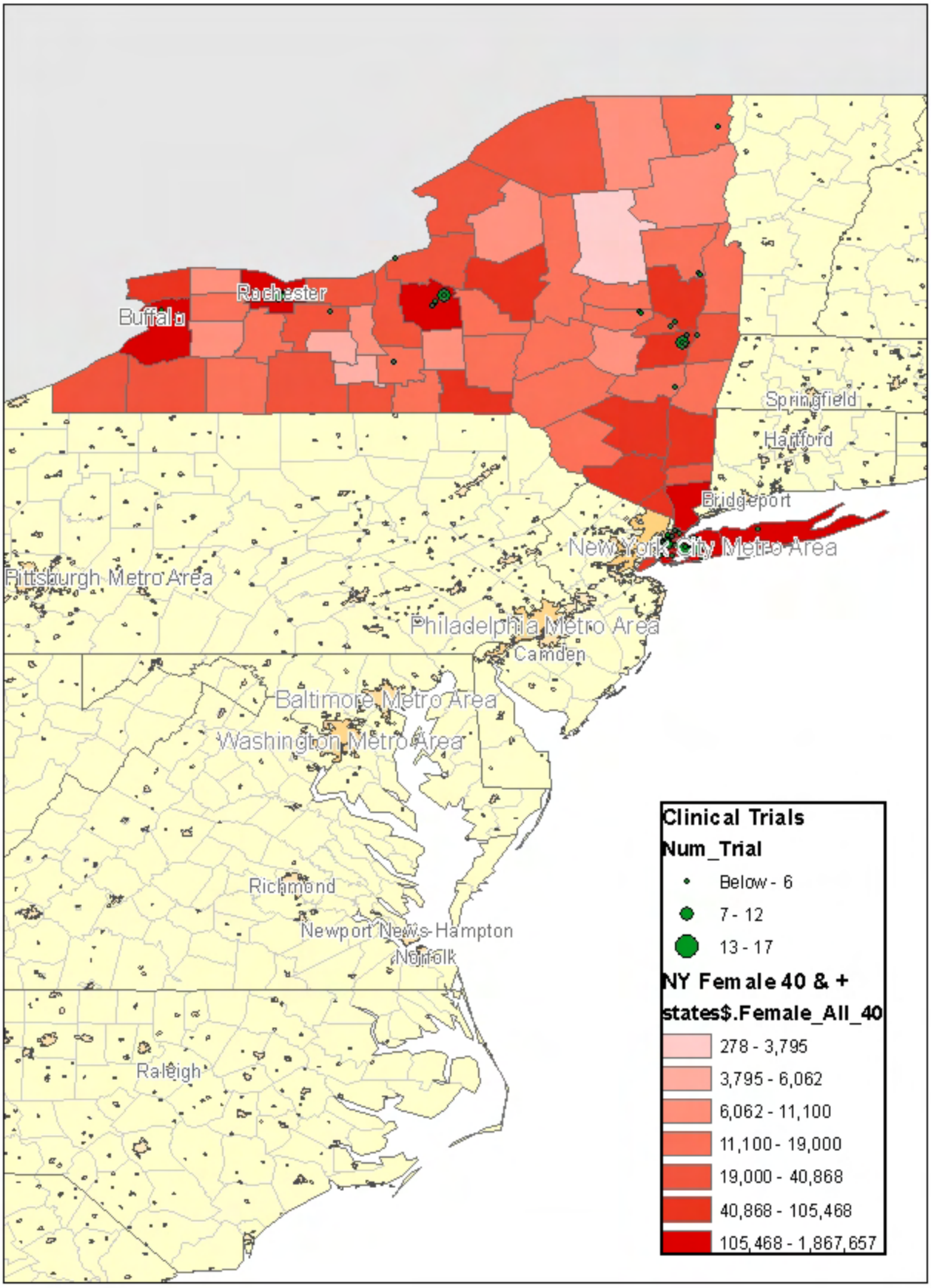
19,000 - 40,868
40,868 - 105,468
105,468 - 1,867,657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11,100 - 19,000
19,000 - 40,868
40,868 - 105,468
105,468 - 1,867,657

Appendix 4:
Print version of Physician Survey

The Inclusion of Minority Patients in Breast Cancer Clinical Trials

University of California
San Francisco
Department of Medicine

Thank you for taking time to complete this short survey about the referral of ethnic minorities into breast cancer clinical trials. Your experiences and insights will help us to better understand the barriers and facilitators that minorities face in participating in clinical trials. We hope that the data collected through these interviews will help enhance minority participation in breast cancer clinical trials.

Your answers will be kept completely confidential. Your individual privacy will be maintained in all published and written data resulting from the study. Your participation in the survey is voluntary.

As a token of our appreciation, you will receive a $10.00 gift card to Amazon.com upon completing and returning the survey. In addition, you will be entered into a raffle to win an Apple iPod. It should take less than 10 minutes to answer all of the questions.

To learn more about this study, visit: *www.dgim.ucsf.edu/diversity/physiciansurvey.html.*

If you have any questions regarding the study or would like to speak to Dr. Celia Kaplan, please contact her by e-mail at *celia.kaplan@ucsf.edu* or by phone at (415) 502-5601.

If you do not treat patients with breast cancer, please let us know by returning this survey in the return envelope provided.

Section A. Your work-related time and specialty

1. On average, what percentage of your work-related time each week do you spend in...

a.	Patient care *(e.g., seeing patients, calling consultants, reviewing lab results)*	☐☐☐ %
b.	Teaching activities	☐☐☐ %
c.	Research activities	☐☐☐ %
d.	Administrative activities *(committee and other profesionally-related activities)*	☐☐☐ %
	Total should add to	**1 0 0 %**

2. What is your primary medical specialty? *Please check **one** answer only.*

- ☐ 1 Surgery
- ☐ 2 Radiation Oncology
- ☐ 3 Hematology/Oncology
- ☐ 4 Other specialty _____ *please specify*

3. Are you board-certified in your specialty?

- ☐ 1 Yes
- ☐ 0 No

4. On average, how many breast cancer patients (newly diagnosed or undergoing treatment, and including those with ductal carcinoma *in situ*) do you treat at your primary practice site per month?

_____ *breast cancer patients per month*

If you **do not treat patients with breast cancer**, *please* **stop here** *and return the survey. Thank you.*

Section B. Characteristics of your primary practice site, patients and staff

5. Which ***one*** of the following best describes your primary practice site?

- ☐ 1 Solo practice
- ☐ 2 Single-specialty group practice
- ☐ 3 Multi-specialty group practice
- ☐ 4 Staff-model HMO (e.g., Kaiser Permanente)
- ☐ 5 Public/community health center
- ☐ 6 Public hospital
- ☐ 7 VA hospital/clinic
- ☐ 8 University/medical school-based practice (not including public or VA hospitals)
- ☐ 9 Other setting _____ *please specify*

6. How many years have you practiced at your ***primary practice site***?

_____ *years*

7. In ***what year*** did you graduate from medical school?

_____

8. In ***which country*** did you graduate from medical school? *Please check **one** answer only.*

- ☐ 1 United States
- ☐ 2 Canada
- ☐ 3 Other country _____ *please specify*

9. In ***what year*** were you born?

_____

10. Are you Latino/a or Hispanic?

- ☐ 1 Yes
- ☐ 0 No

11. What is your race/ethnicity? *Please check **one** answer only.*

- ☐ 1 Black or African American
- ☐ 2 Asian, Asian American or Pacific Islander
- ☐ 3 White, European American or Caucasian
- ☐ 4 American Indian or Alaska Native
- ☐ 5 Other _____ *please specify*

12. What percentage of your patients is insured by...

a.	Medicare (including supplemental insurance)	☐☐☐ %
b.	Medicaid	☐☐☐ %
c.	Private insurance or HMO (including Kaiser)	☐☐☐ %
d.	No insurance/free care/self-pay	☐☐☐ %
	Total should add to	**1 0 0 %**

13. What percentage of your patients is...

a.	Black or African American	☐☐☐ %
b.	Asian, Asian American or Pacific Islander	☐☐☐ %
c.	Latino/a or Hispanic	☐☐☐ %
d.	White, European American, or Caucasian	☐☐☐ %
e.	Other	☐☐☐ %
	Total should add to	**1 0 0 %**

14. What percentage of your patients ***requires*** interpretation of a language other than English to receive health care services? *Write **"0"** if all of your patients speak English.*

_____ %

15. Other than English, do you speak any of the following languages with your patients?

		Yes	No
a.	Spanish	☐ 1	☐ 0
b.	Chinese (Cantonese or Mandarin)	☐ 1	☐ 0
c.	Tagalog	☐ 1	☐ 0
d.	Vietnamese	☐ 1	☐ 0
e.	Korean	☐ 1	☐ 0
f.	Russian	☐ 1	☐ 0
g.	Other language(s) *please specify* _____	☐ 1	☐ 0

16. Do your patients speak any of the following languages as their primary language?

		Yes	No
a.	Spanish	☐ 1	☐ 0
b.	Chinese (Cantonese or Mandarin)	☐ 1	☐ 0
c.	Tagalog	☐ 1	☐ 0
d.	Vietnamese	☐ 1	☐ 0
e.	Korean	☐ 1	☐ 0
f.	Russian	☐ 1	☐ 0
g.	Other language(s) *please specify* _____	☐ 1	☐ 0

17. Are any of the following language interpreter services available at your primary practice site?

		Yes	No
a.	Interpretation by bilingual staff, including yourself ***(NOT** a professional interpreter)*	☐ 1	☐ 0
b.	Volunteer onsite interpreters ***(NOT** staff)*	☐ 1	☐ 0
c.	Professional onsite interpreters	☐ 1	☐ 0
d.	Professional interpreter services by telephone or video	☐ 1	☐ 0

18. Does your primary practice site have a bilingual (English and any other language) staff person (including yourself) in any of the following positions?

		Yes	No	No staff in this position
a.	Receptionist, front desk or appointment desk	☐ 1	☐ 0	☐ 99
b.	Nurse, nursing assistant, medical assistant	☐ 1	☐ 0	☐ 99
c.	Physician, physician's assistant or nurse practitioner	☐ 1	☐ 0	☐ 99
d.	Laboratory assistant	☐ 1	☐ 0	☐ 99
e.	Other staff _____ *please specify*	☐ 1	☐ 0	☐ 99

18a. If you answered **"Yes"** to any of the above in Question 18: Which of the following languages does your staff person(s) speak? *Please skip to Question 19 if you did **not** answer **"Yes"**.*

		Yes	No
a.	Spanish	☐ 1	☐ 0
b.	Chinese (Cantonese or Mandarin)	☐ 1	☐ 0
c.	Tagalog	☐ 1	☐ 0
d.	Vietnamese	☐ 1	☐ 0
e.	Korean	☐ 1	☐ 0
f.	Russian	☐ 1	☐ 0
g.	Other language(s) *please specify* _____	☐ 1	☐ 0

19. Does your office make available to your patients any educational materials about breast cancer (screening, prevention, and treatment) in any of the following languages?

	Yes	No
a. English	☐ 1	☐ 0
b. Spanish	☐ 1	☐ 0
c. Chinese (Cantonese or Mandarin)	☐ 1	☐ 0
d. Tagalog	☐ 1	☐ 0
e. Vietnamese	☐ 1	☐ 0
f. Korean	☐ 1	☐ 0
g. Russian	☐ 1	☐ 0
h. Other language(s) *please specify* _____	☐ 1	☐ 0

Section C. Your involvement in research

20. Please tell us about your interaction with university medical centers

	Yes	No
a. Do you have a faculty appointment at a medical school?	☐ 1	☐ 0
b. Do you have admitting privileges at a university medical school or major teaching affiliate?	☐ 1	☐ 0
c. In the past two years, have you consulted with a physician at a university medical center about the care of any of your patients?	☐ 1	☐ 0

21. ***In the past two years***, how many breast cancer clinical trials have you been involved in as a principal investigator or co-investigator? *If none, please enter* ***"0"***.

_____ *breast cancer clinical trials*

22. Have you ever participated ***as a patient*** in a clinical trial for any type of therapy or treatment?

☐ 1 Yes
☐ 0 No

Section D. Clinical trial referral and recruitment

23. With respect to breast cancer clinical trials, ***in the past year*** have you...

	Yes	No
a. ...had patients inquire about breast cancer clinical trials?	☐ 1	☐ 0
b. ...referred or recruited patients to breast cancer clinical trials administered by others?	☐ 1	☐ 0
c. ...recruited patients for a breast cancer clinical trial for which you were principal investigator or co-investigator?	☐ 1	☐ 0

24. ***In the past year***, have you referred or recruited patients to breast cancer clinical trials sponsored by the...

	Yes	No
a. National Cancer Institute (NCI)	☐ 1	☐ 0
b. NCI Clinical Trial Cooperative Groups (e.g., ECOG, NSABP)	☐ 1	☐ 0
c. Pharmaceutical/Industry	☐ 1	☐ 0
d. I have referred or recruited but do not know who sponsored the study	☐ 1	☐ 0

25. How often ***in the past year*** have you done the following ***with your breast cancer patients***?

	Very often	Often	Some times	Rarely	Never
a. Discussed the possibility of enrolling them in breast cancer clinical trials	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b. Given them informational resources (e.g., brochures internet referrals) about breast cancer clinical trials	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c. Discussed with them the potential benefits and risks/burdens of a specific breast cancer clinical trial	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
d. Obtained their permission to have a staff person from a breast cancer clinical trial contact them	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

26. ***In the past year***, have you referred or recruited patients to any of the following types of breast cancer clinical trials? *Please check all that apply.*

	Yes	No
a. Adjuvant or neoadjuvant therapy	☐ 1	☐ 0
b. Surgical	☐ 1	☐ 0
c. Radiation	☐ 1	☐ 0
d. Chemotherapy	☐ 1	☐ 0
e. Biological therapy or immunotherapy	☐ 1	☐ 0
f. Hormonal therapy	☐ 1	☐ 0
g. Stem cell or bone marrow	☐ 1	☐ 0
h. Supportive care (e.g., treatments to manage clinical trial side effects)	☐ 1	☐ 0
i. Prevention trials	☐ 1	☐ 0
j. Other types of trials _____ *please specify*	☐ 1	☐ 0

27. ***In the past year***, how many patients have you enrolled or referred to breast cancer clinical trials? *Write* ***"0"*** *if you did not enroll or refer any patients.*

_____ *patients*

28. In your experience, who typically initiates a discussion about breast cancer clinical trials? *Please check* ***one*** *answer only.*

☐ 1 My patients initiate the discussion
☐ 2 I initiate the discussion
☐ 3 My patient and I both initiate the discussion
☐ 4 I do not discuss clinical trials with my patients

29. In general, to what degree is each of these factors a barrier for you in referring or recruiting a breast cancer patient to a clinical trial?

	not a barrier ⟷ a major barrier				
a. Eligibility or study entry criteria of cancer clinical trials	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b. My concern that trial treatment will be inferior to standard treatments	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c. My concern that patients referred to trials will not return to my practice	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
d. Time and effort required to explain trials to a patient	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
e. My concern about inadequate reimbursement from research sponsors	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
f. A lack of time dedicated for research	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
g. My concern that trials cannot accommodate non-English speakers	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
h. My concern that the risks of current trials outweigh the benefits	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
i. Most of the trials I have seen offer little or no benefit over standard treatment	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
j. A lack of information about trials	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
k. Patient's lack of adequate insurance coverage	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
l. Patient's lack of understanding of what clinical trials are	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
m. Patient's lack of transportation	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
n. Patient's possible non-adherence with the study protocol	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
o. Patient's reluctance to complete paperwork	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
p. Patient's inability to take time from work, family or other duties	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

30. In general, to what degree would the following factors serve as an incentive for you to refer or recruit a breast cancer patient to a clinical trial?

	not an incentive ⟷ a major incentive				
a. The clinical trial is likely to improve the patient's medical condition	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b. Patient's lack of other means to pay for health care	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c. Patient's desire to take advantage of the latest available treatment options	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
d. Lack of other effective treatment options	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
e. Prevention of a recurrence or second cancer	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
f. Patient would have access to a drug that is difficult to get authorization for outside of a clinical trial	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

You have completed our survey.
Thank you for your time and assistance!

Please return this questionnaire in the envelope provided.

As a token of our appreciation, you will receive a
$10.00 gift card to Amazon.com.
In addition, you will be entered into a raffle to win an Apple iPod.

UCSF
University of California
San Francisco
Department of Medicine

Appendix 5:
Web version of Physician Survey

You have completed 0 % of the survey.

University of California
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THE INCLUSION OF MINORITY PATIENTS IN BREAST CANCER CLINICAL TRIALS

Thank you for taking time to complete this short survey about the participation of ethnic minorities in breast cancer clinical trials. Your experiences and insights will help us to better understand the barriers and facilitators that minorities face in participating in clinical trials. We hope that the data collected through these interviews will help enhance minority participation in breast cancer clinical trials.

Your answers will be kept completely confidential. Your individual privacy will be maintained in all published and written data resulting from the study. Any identifiable information, including your email and IP addresses, will not be shared with any third party and will be stored separately from your responses. Your participation in the survey is voluntary.

As a token of our appreciation, you will receive a **$10.00 gift card to Amazon.com** upon completing the survey. In addition, you will be entered into a **raffle to win an Apple Ipod**.

To learn more about this study, please visit the study's website. If you have any questions regarding the study or would like to speak to Dr. Celia Kaplan, please contact her by e-mail or by phone at (415) 502-5601.

Survey Instructions:

It should take less than 10 minutes to answer all of the questions. Please use the "Previous" and "Next" buttons to navigate through the survey.

Log-in: Survey ID and Password

1. To begin the survey, please enter your survey ID.

   ID:

2. Please enter the survey password.

   Password:

Section A. Your work-related time and specialty

3. On average, what percentage of your work-related time each week do you spend in ...

a.	Patient care (e.g., seeing patients, calling consultants, reviewing lab results)	%
b.	Teaching activities	%
c.	Research activities	%
d.	Administrative activities (committee and other professionally-related activities)	%

Total should add to 100%.

4. What is your primary medical specialty? *Please check **one** answer only.*

- ○ Surgery
- ○ Radiation Oncology
- ○ Hematology/Oncology
- ○ Other specialty - *please specify:* _____

5. Are you board-certified in your specialty?

- ○ Yes
- ○ No

6. On average, how many breast cancer patients (newly diagnosed or undergoing treatment, and including those with ductal carcinoma *in situ*) do you treat at your primary practice site per month?

_____ breast cancer patients per month

Section B. Characteristics of your primary practice site, patients and staff

7. Which ***one*** of the following best describes your primary practice site?

- ○ Solo practice
- ○ Single-specialty group practice
- ○ Multi-specialty group practice
- ○ Staff-model HMO (e.g., Kaiser Permanente)
- ○ Public/Community health center
- ○ Public hospital
- ○ VA hospital/clinic
- ○ University/medical school-based practice (not including public or VA hospitals)
- ○ Other setting - *please specify:* _____

8. How many years have you practiced at your ***primary practice site***?

_____ years

9. In ***what year*** did you graduate from medical school?

_____

10. In ***which country*** did you graduate from medical school?

- ○ United States
- ○ Canada
- ○ Other country - *please specify:* _____

11. In ***what year*** were you born?

_____

12. Are you Latino/a or Hispanic?

- ○ Yes
- ○ No

13. What is your race/ethnicity? *Please check **one** answer only.*

- ○ Black or African American
- ○ Asian, Asian American or Pacific Islander

- White, European American or Caucasian
- American Indian or Alaska Native
- Other - *please specify:*

14. What percentage of your patients is insured by…
Please give your best estimate.

a. Medicare (including supplemental insurance)	%
b. Medicaid	%
c. Private insurance or HMO (including Kaiser)	%
d. No insurance/free care/self-pay	%

Total should add to 100%.

15. What percentage of your patients is ...
Please give your best estimate.

a. Black or African American	%
b. Asian, Asian American or Pacific Islander	%
c. Latino/a or Hispanic	%
d. White, European American, or Caucasian	%
e. Other	%

Total should add to 100%.

16. What percentage of your patients ***requires*** interpretation of a language other than English to receive health care services?
*Write "**0**" if all your patients speak English.*

%

17. Other than English, do you speak any of the following languages with your patients?

	Yes	No
a. Spanish		
b. Chinese (Cantonese or Mandarin)		
c. Tagalog		
d. Vietnamese		
e. Korean		
f. Russian		
g. Other language(s)		

18. What other language(s) do you speak with your patients?

19. Do your patients speak any of the following languages as their primary language?

Yes	No

a. Spanish	○	○
b. Chinese (Cantonese or Mandarin)	○	○
c. Tagalog	○	○
d. Vietnamese	○	○
e. Korean	○	○
f. Russian	○	○
g. Other language(s)	○	○

20. What other language(s) do your patients speak as their primary language?

21. Are any of the following language interpreter services available at your primary practice site?

	Yes	No
a. Interpretation by bilingual staff, including yourself *(**NOT** a professional interpreter)*	○	○
b. Volunteer onsite interpreters (***NOT** staff*)	○	○
c. Professional onsite interpreters	○	○
d. Professional interpreter services by telephone or video	○	○

22. Does your primary practice site have a bilingual (English and any other language) staff person (including yourself) in any of the following positions?

	Yes	No	No staff in this position
a. Receptionist, front desk or appointment desk	○	○	○
b. Nurse, nursing assistant, medical assistant	○	○	○
c. Physician, physician's assistant or nurse practitioner	○	○	○
d. Laboratory assistant	○	○	○
e. Other staff	○	○	○

23. What other bilingual staff position(s) do you have at your primary practice site?

24. Which of the following languages does your staff person(s) speak?

	Yes	No
a. Spanish	○	○
b. Chinese (Cantonese or Mandarin)	○	○
c. Vietnamese	○	○
d. Russian	○	○
e. Korean	○	○
f. Other language(s)	○	○

25. What other language(s) does your staff person(s) speak?

26. Does your office make available to your patients any educational materials about breast cancer (screening, prevention, and treatment) in any of the following languages?

	Yes	No
a. English	○	○
b. Spanish	○	○
c. Chinese (Cantonese or Mandarin)	○	○
d. Vietnamese	○	○
e. Russian	○	○
f. Korean	○	○
g. Other language(s)	○	○

27. In what other language(s) do you make educational materials about breast cancer available to your patients?

Section C. Your involvement in research

28. Please tell us about your interaction with university medical centers.

	Yes	No
a. Do you have a faculty appointment at a medical school?	○	○
b. Do you have admitting privileges at a university medical school or major teaching affiliate?	○	○
c. In the past two years, have you consulted with a physician at a university medical center about the care of one of your patients?	○	○

29. ***In the past two years***, how many breast cancer clinical trials have you been involved in as a principal investigator or co-investigator? *If none, please enter "**0**".*

breast cancer clinical trials

30. Have you ever participated ***as a patient*** in a clinical trial for any type of therapy or treatment?

- ○ Yes
- ○ No

Section D. Clinical trial referral and recruitment (Final Section)

31. With respect to breast cancer clinical trials, ***in the past year*** have you ...

	Yes	No
a. ... had patients inquire about breast cancer clinical trials?	○	○
b. ... referred or recruited patients to breast cancer clinical trials administered by others?	○	○
c. ... recruited patients for a breast cancer clinical trial for which you were principal investigator or co-investigator?	○	○

32. ***In the past year***, have you referred or recruited patients to breast cancer clinical trials sponsored by

the ...

	Yes	No
a. National Cancer Institute (NCI)	○	○
b. NCI Clinical Trial Cooperative Groups (e.g., ECOG, NSABP)	○	○
c. Pharmaceutical/Industry	○	○
d. I have referred but I don't know who sponsored the study	○	○

33. How often ***in the past year*** have you done the following ***with your breast cancer patients***?

	Very Often	Often	Sometimes	Rarely	Never
a. Discussed the possibility of enrolling them in breast cancer clinical trials	○	○	○	○	○
b. Given them informational resources (e.g., brochures, internet referrals) about breast cancer clinical trials	○	○	○	○	○
c. Discussed with them the potential benefits and risks/burdens of a specific breast cancer clinical trial	○	○	○	○	○
d. Obtained their permission to have a staff person from a breast cancer clinical trial contact them	○	○	○	○	○

34. ***In the past year***, have you referred or recruited patients to any of the following types of breast cancer clinical trials? *Please check all that apply.*

	Yes	No
a. Adjuvant or neoadjuvant therapy	○	○
b. Surgical	○	○
c. Radiation	○	○
d. Chemotherapy	○	○
e. Biological therapy or immunotherapy	○	○
f. Hormonal therapy	○	○
g. Stem cell or bone marrow	○	○
h. Supportive care (e.g., treatments to manage clinical trial side effects)	○	○
i. Prevention trials	○	○
j. Other types of trials	○	○

35. What other types of breast cancer clinical trials have you referred patients to?

36. ***In the past year***, how many patients have you enrolled or referred to breast cancer clinical trials? *Write "**0**" if you did not enroll or refer any patients.*

patients

37. In your experience, who typically initiates a discussion about breast cancer clinical trials? *Please check **one** answer only.*

- My patients initiate the discussion
- I initiate the dicussion
- My patient and I both initiate the discussion
- I do not discuss trials with patients

38. In general, to what degree is each of these factors a barrier for you in referring or recruiting a breast cancer patient to a clinical trial?

	Not a barrier	**<----------**	**----------**	**---------->**	**A major barrier**
a. Eligibility or study entry criteria of cancer clinical trials					
b. My concern that trial treatment will be inferior to standard treatments					
c. My concern that patients referred to trials will not return to my practice					
d. Time and effort required to explain trials to a patient					
e. My concern about inadequate reimbursement from research sponsors					
f. A lack of time for research					
g. My concern that trials cannot accommodate non-English speakers					
h. My concern that the risks of current trials outweigh the benefits					
i. Most of the trials I have seen offer little or no benefit over standard treatment					
j. A lack of information about trials					
k. Patient's lack of adequate insurance coverage					
l. Patient's lack of understanding of what clinical trials are					
m. Patient's lack of transportation					
n. Patient's possible non-adherence with the study protocol					
o. Patient's reluctance to complete paperwork					
p. Patient's inability to take time from work, family or other duties					

39. In general, to what degree would the following factors serve as an incentive for you to refer or recruit a breast cancer patient to a clinical trial?

	Not an incentive	**<----------**	**----------**	**---------->**	**A major incentive**
a. The clinical trial is likely to improve the patient's medical condition					
b. Patient's lack of other means to pay for health care					
c. Patient's desire to take advantage of the latest					

	available treatment options					
d.	Lack of other effective treatment options	○	○	○	○	○
e.	Prevention of a recurrence or second cancer	○	○	○	○	○
f.	Patient would have access to a drug that is difficult to get authorization for outside of a clinical trial	○	○	○	○	○

40. **You have reached the end of this survey.** As a token of our appreciation, you will receive a $10.00 gift card to Amazon.com. Please select whether you would like to receive the gift card by mail or by e-mail.

- ○ Please send the gift card to me by mail.
- ○ Please e-mail my gift card to this e-mail address: [ ]

To submit your survey, please click on the submit button below. We thank you for your time and assistance with this study.
